## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventors: White et al. Confirm. No.: 9053

Serial No.: 10/535,748 Examiner: SKOWRONEK, Karlheinz R.

Filing Date: September 27, 2005 Group: 1631

Title: ELECTRO-OPTICAL NUCLEIC ACID-BASED SENSOR ARRAY

AND METHOD FOR DIRECTING ANALYTES

## DECLARATION BY DR. GARY SETTLES UNDER 37 C.F.R. 1.132

I, Gary Settles, Ph.D. pursuant to 37 C.F.R. § 1.132, hereby declare that:

- I am currently a Distinguished Professor of Mechanical Engineering at The Pennsylvania
  State University, University Park, PA. I received my Ph.D. in Aerospace and Mechanical
  Sciences from Princeton University in 1976.
- During my over three decades of research, I have studied and I am still actively studying fluid dynamics. My research has included at least the following topics in the area of fluid dynamics: Cargo Explosive Trace Detection; Exploratory Research On Supersonic Abrasive Ice-Blasting; Research on the Atomization of Liquid Metals To Produce Fine Powders; Research on Assist-Gas Dynamics and Nozzle Design for Laser Cutting; Full-Scale Visualization of Kitchen Ventilation Air Currents; Gas Dynamics of Soot Blower Nozzles; Abrasive Blasting Nozzle Development; Dross Formation in Plasma Cutting; Research on the Transfer Efficiency of Airless Spray Painting; Research on Combustion-Driven HVOF Thermal Sprays; Research on

the Aerodynamics of Explosive Detection Portals for Aviation Security Screening; Thermofluid Dynamics: CD-ROMs For Engineering Education; Hypermedia Flow Visualization Project For; Compressible Flow Instruction; Aerodynamics of Canine Olfaction for Unexploded Ordnance Detection, Research to Adapt Known Optical Shock-Wave Imaging Technology For Aviation Security Purposes; Airflow Visualization In A Model Greenhouse; and Schlieren Imaging of Shock Waves and Related Flow Phenomena In Trumpet Playing.

- 3. Over the past more than three decades, I have published numerous articles in my field in peer reviewed journals.
- 4. I was chosen by the American Society of Mechanical Engineers (ASME) as the 2004 Freeman Scholar. This is one of the major prizes awarded by ASME, given only every second year, to recognize "a person of high capability and considerable experience in the area of fluids engineering."
- A true copy of my curriculum vitae with a list of publications is attached herewith as 5. Exhibit A.
- 6. I am aware of the nucleic acid-based sensing apparatus claimed in the above-identified patent application.
- 7. I have collaborated with Drs. Kauer and White on projects related to this invention. Over a period of several years I have helped them with aerodynamic aspects of first the Tufts Medical Nose and later a device developed by Cogniscent Inc. However, I have been involved only with the fluid flow, not with the DNA or other sensor chemical or biochemical aspects.
- I have been advised that the Examiner of the above-identified patent application has cited 8. U.S. Patent No. 7,029,852 to Liebholz et al. ("Liebholz") and U.S. Patent No. 6,057,100 to Heynecker ("Heynecker").

- 9. I have reviewed both Liebholz and Heynecker.
- 10. I have been advised that the Examiner asserted that "it would have been obvious to modify the sensor apparatus of Liebholz with the nucleic acid microarray substrates of Heynecker because all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective function; the combination would have yielded nothing more than predictable results to one of ordinary skill in the art at the time of the invention."
- 11. I respectfully disagree with the Examiner's analysis for the following reasons.
- 12. The apparatus described in Liebholz relies on impingement of particles to a surface for their detection (see, e.g. col. 2, lines 43-46). The apparatus directs harmful agents onto a non-living bioreceptor surface for use in detecting and classifying them (see, e.g. col. 3, lines 50-54. Liebholz also determines that the term "bioreceptor" refers to a substrate containing a set of chosen sensor molecules (see, col. 3, lines 54-56).
- 13. The function of Liebholz apparatus requires that the particles must be impinged on the surface. This means that the surface should be solid, such as glass or plastic. Such surfaces are also described in Liebholz (see, col. 4, lines 7-10).
- 14. Thus, Liebholz works by relying on impingement of particles on a surface. Therefore, a surface that is porous, would not be an ideal surface. This is because many of the particles, such as particles under 10 µm as described by Liebholz, would pass through such a porous substrate and not be impinged on the substrate. This is exemplified by Liebholz, for example, when they describe an optional mechanical filter (see, e.g., col. 4, lines 10-16 and col. 7, lines 8-23). Accordingly, a skilled artisan would not substitute the solid substrate surface with a porous substrate surface because such a surface would be much less efficient in capturing particles of

the size under  $10\mu m$ , such as particles of 1-5  $\mu m$  in diameter as described by Liebholz (see, e.g.,

col. 4, lines 14-16, and col. 6, lines 48-51). This is because while some of the particles would

get stuck on the porous surface, many of them would go through.

15. In summary, a skilled artisan would not replace the glass or plastic surface of Liebholz

apparatus with a porous surface because such a substitution would render the Liebholz apparatus

much less efficient in impinging particles on the surface with a substrate. For the same reason, a

skilled artisan would not have considered combining Liebholz and Heynecker.

I hereby declare that all statements made herein of my own knowledge are true; and further

that these statements were made with the knowledge that willful false statements and the like so

made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United

States Code and that any such willful false statements may jeopardize the validity of the

application or any patent issued thereon.

April 3, 2008

Date

Gary Settles, Ph.D.